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(71) Applicant: **TELECTRONICS N.V.**
De Ruyterkade 58A P.O. Box 837
Curaçao (AN)

(72) Inventor: **Collins, Kenneth A.**
41 Shellcove Road
Neutral Bay, N.S.W. 2080 (AU)
Inventor: **Maker, Philip John**
22/15 Lachlan Avenue
North Ryde, Sydney (AU)

(74) Representative: **Sturt, Clifford Mark et al**
MARKS & CLERK 57-60 Lincoln's Inn Fields
London WC2A 3LS (GB)

(54) **Implantable automatic and haemodynamically responsive cardioverting/defibrillating pacemaker with means for minimizing bradycardia support pacing voltages.**

(57) An implantable, battery-operated cardioverting/defibrillating pacemaker device with the ability to sense and respond to haemodynamic compromise is described. The ventricular pressure (VP) and electrical activity of the heart are sensed via one or more transvenous or epicardial devices. The filtered peak-to-peak amplitude (VFPPA) and a peak pressure function (VPPF) based upon the right and/or left VP waveform(s) are derived. One of the VFPPA and VPPF, and electrically derived heart rate information, are used in the diagnosis of arrhythmic states. Bradycardia support pacing is initiated and terminated by reference to the VP signal, and the pacing pulse voltage used during bradycardia support pacing is optimized in order to extend battery life of the device. This is done by using the haemodynamic sensor to confirm the presence of an appropriate haemodynamic response to the delivery of bradycardia support pacing, and adjusting the pacing voltage to its lowest efficacious level. In the preferred embodiment the high pass filtered right ventricular pressure is monitored to confirm pacing capture.

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This invention relates to an implantable cardioverting/defibrillating pacemaker and, more particularly, to a pacemaker of this type that is responsive to both an electrically derived heart rate and to a haemodynamic parameter.

An implantable haemodynamic cardioverting/defibrillating pacemaker is disclosed in United States Patent Application No. 481,364 to K. A. Collins, filed February 19, 1990, and entitled "An Implantable Automatic and Haemodynamically Responsive Cardioverting/Defibrillating Pacemaker," which is assigned to the assignee of the present invention, and is incorporated herein by reference. The pacemaker of said Application No. 481,364 overcomes many of the problems of false or inappropriate delivery of therapy that arise out of a reliance solely upon the sensing of the electrical activity of the heart as a means of determining the state of cardiac function.

Among the significant problems that face such an implantable device is the problem of increasing the device's battery life. Research has shown that bradycardia support pacing, in a cardioverting/defibrillating pacemaker, can consume between 10 and 30 percent of the total battery life of the device, depending on the pacing voltage used. Minimizing the battery consumption due to bradycardia support pacing will help reduce the risk of premature depletion of the battery of the device. At best, premature depletion forces the recipient of the device to undergo another general anesthetic. At worst, it may result in the death of the patient. Williams et al. in their article "Automatic Implantable Cardioverter-Defibrillator-Related Complications", J.A.C.C., Vol. 15 (2), Page 55A (1990), report that the death rate due to premature battery depletion in such devices was 0.6 percent.

It is well known that under different circumstances greater pacing energies are required. For example, after reversion of ventricular fibrillation, bradycardia support pacing often requires an increased pacing energy. One means of increasing pacing energies during a period of post reversion asystole is disclosed in the United States Patent No. 4,869,252 of Norma L. Gilli, dated September 26, 1989, which patent is assigned to the assignee of the present invention. In the disclosure of said Gilli patent, maximum pacing energies are provided regardless of the state of the heart. The Gilli patent also reveals a method for controlling pulse energy in antitachyarrhythmia and bradycardia support pacing. However, the Gilli patent is limited in that no means are provided for assuring that the capture of the heart is occurring, nor is any means provided therein for determining how low a pacing voltage can safely be used to ensure capture of the heart.

Mirowski et al., in United States Patents Nos. 3,614,955 and 3,942,536, describe systems that sense heart function using the peak of the right ventricular pressure waveform. These devices suffer some obvious disadvantages including, among others, the fact that no haemodynamic parameters are provided to control the pacing voltage used during bradycardia support pacing.

A device disclosed in United States Patent No. 4,774,950, to Cohen, has sought to overcome the shortcomings of common forms of cardioverting/defibrillating pacemakers by relying on the mean right ventricular pressure, mean arterial pressure, mean left atrial pressure, mean left ventricular pressure and/or mean central venous pressure as indicators of haemodynamic compromise. Background material relating to the Cohen invention can be found in an article by Cohen et al., entitled "Haemodynamic Responses to Rapid Pacing: A Model for Tachycardia Differentiation", PACE, Vol. 11, Pages 1522-1528 (1988). The Cohen device also is devoid of disclosure relating to the use of haemodynamic parameters to control the pacing voltage used during bradycardia support pacing.

As indicated earlier, one means of minimizing the energy consumed in bradycardia support pacing, and thereby extending the battery life of the pacemaker, is to reduce the pacing voltage used. In order to do this, the implantable device must have some means of determining whether or not the delivered pacing pulse has stimulated the heart to beat, i.e., determining whether or not the heart has been captured. In a haemodynamic cardioverting/defibrillating pacemaker, the signal from which the haemodynamic parameter is being derived can be used to determine whether or not the pacing pulse has captured the heart. A response to pacing, such as a pulsatile rise in the right ventricular pressure, can be used to confirm capture. The bradycardia support pacing voltage can thereafter be reduced until capture is lost, and then raised again to the lowest effective pacing voltage.

It is, therefore, a primary object of the present invention to provide an improved implantable, battery-operated device for the treatment of a malfunctioning heart that is capable of providing effective bradycardia support pacing at a lower mean energy level than has heretofore been the case in order to provide for increased battery life of the device.

Another object of the present invention is to provide an improved implantable, battery-operated device for the treatment of a malfunctioning heart, which device has sensing modalities for sensing both the heart's electrical function and its haemodynamic function, and which device utilizes sensed haemodynamic function information to enable it reduce the bradycardia support pacing voltage to the lowest effective level.

A further object of the present invention is to provide a two-sensing-modality, cardioverting/defibrillating pacemaking device in which the energy required for bradycardia support pacing can be minimized by sensing

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responses are the responses of the heart, once captured, to the pacing pulses delivered. There are many possible evoked responses: the main meaning being the electrophysiological response. In this disclosure the evoked response referred to is usually the initiation of ventricular contraction, as witnessed by the development of a pressure pulse within the ventricle.

Briefly stated, and in accordance with one embodiment of the invention, there is provided an implantable, battery-operated device for the treatment of a malfunctioning heart. The device includes a first sensing modality for sensing an electrical function in a patient's heart and providing a first signal representative of the electrical function, and a second sensing modality for sensing a haemodynamic function in the patient's heart and providing a second signal representative of the haemodynamic function. The device is also provided with a first means responsive to the first signal for analyzing the state of the heart's function and providing any required electrical shock pacing therapy to the heart at an initial predetermined energy level high enough to ensure prompt pacing capture of the heart. The device further includes a second means responsive to the second signal, and operative when evoked haemodynamic responses from the pacing therapy are sensed, to cause the energy level of the pacing therapy provided by the first means to be reduced from its initial predetermined level to a lower level, at which level pacing capture of the heart can be maintained and battery life of the device is increased relative to the battery life obtainable at the initial predetermined energy level.

In accordance with another embodiment, the invention provides a method of optimizing bradycardia support pacing voltages delivered to a patient's heart including the steps of (A) delivering a chain of bradycardia support pacing pulses at a predetermined voltage level to the heart; (B) monitoring the ventricular pressure waveform of the heart to assess whether or not pacing capture of the heart occurs during delivery of the chain of pulses; (C) if pacing capture of the heart occurs during step (B), decreasing the level of the bradycardia support pacing voltage delivered in step (A) to a minimum level, at which pacing capture is lost, and then raising the level of such voltage to an intermediate level, at which effective pacing capture is again achieved; and, (D) if pacing capture does not occur during steps (A) and (B), increasing the level of the bradycardia support pacing voltage delivered under step (A) until pacing capture of the heart occurs under step (B).

In accordance with yet another embodiment, the invention provides a method for determining the need for bradycardia support pacing of a patient's heart including the steps of (A) continuously monitoring a signal derived from a haemodynamic pressure waveform of the patient; (B) comparing the monitored signal with a predetermined threshold value; (C) detecting when the threshold value is crossed by the monitored signal to determine when heart contractions have occurred; and, (D) initiating bradycardia support pacing in the event a threshold crossing does not occur within a predetermined time period following the time at which a last-detected threshold crossing occurred, or within a predetermined time period following a last-detected heart contraction.

In accordance with a still further embodiment, the invention provides a method for determining the need for continuing ongoing bradycardia support pacing of a patient's heart including the steps of (A) continuously monitoring a signal derived from a haemodynamic pressure waveform of the patient during the application to the heart of bradycardia support pacing pulses; (B) comparing the monitored signal with a predetermined threshold value; (C) noting when the threshold value is crossed by the monitored signal to determine when heart contractions have occurred; and, (D) initiating a subsequent bradycardia support pacing pulse in the event a threshold crossing does not occur within a predetermined time period after a last-previous bradycardia support pacing pulse has been delivered.

In accordance with yet a further embodiment, the invention provides a method for terminating ongoing bradycardia support pacing of a patient's heart including the steps of (A) continuously monitoring both a first signal derived from a haemodynamic pressure waveform of the patient and a second signal representing electrical activity of the heart during the application to the heart of bradycardia support pacing pulses; (B) comparing the monitored first signal with a predetermined threshold value, and the monitored second signal with a predetermined QRS-wave complex; and, (C) terminating the bradycardia support pacing if, within a first predetermined time period after a last-previous bradycardia support pacing pulse has been delivered, either the first signal crosses the predetermined threshold value or the second signal displays QRS-wave pattern within the predetermined QRS-wave complex.

While the specification concludes with claims particularly pointing out and distinctly claiming the subject matter of this invention, it is believed that the invention will be better understood from the following description, taken in conjunction with the accompanying drawings, in which:

FIG. 1 is a table of representative RVFPPA and RVPPF values;

FIG. 2 is a schematic diagram of an implanted cardioverting/defibrillating pacemaker device in accordance with the present invention, positioned in the patient's body and showing electrical leads which interconnect the heart and the device;

FIG. 3 is a block diagram of the device shown in FIG. 2, with blocks thereof representing either discrete

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from the filtered and digitized right ventricular pressure (RVP) waveform. The PPU 24 communicates the derived data to the main processing unit (MPU) 20. The MPU 20 has access to the data registers (memory) 24a of the PPU 24.

The RVFPPA is obtained by filtering the RVP waveform with a high-pass filter having a 3 db frequency in the range of 0.1 to 0.5 Hz. In the preferred embodiments of the invention this filter is a second order Butterworth filter. The RVPPF is obtained by rectifying the filtered RVP waveform and then integrating it. The integral for each contraction is obtained by reference to the R-wave interval from the endocardial ECG. In the preferred embodiments of this device both the ECG signal and one or the other of the signals derived from the RVP waveform are used to determine whether or not the recipient of the device is haemodynamically comprised.

The device has two main implementations, each of which can be implemented using one of two algorithms. In the first algorithm (hereinafter referred to as the "simple threshold algorithm") the RVFPPA is monitored and compared to a threshold value. This value can be programmed as either an absolute value or as a percentage of a long term mean of the RVFPPA.

The threshold detector is linked to a simple counter (not shown). Each time the value of the RVFPPA becomes greater than the threshold value, the counter is reset to zero. This counter increments each time the RVFPPA is sensed and found to be lower than the threshold value. If this counter reaches a pre-programmed value, then haemodynamic comprise is deemed to exist. In the normally functioning recipient of this device, the rising edge of the RVFPPA would periodically reset the counter before the triggering value were reached. When the counter reaches the triggering level, the PPU 24 communicates this to the MPU 20, indicating that a state of haemodynamic compromise exists.

In the second algorithm (hereinafter referred as the "X out of Y algorithm"), the RVFPPA is assessed with each heart beat cycle as the sum of the greatest negative and positive digital values obtained over one cycle. The value is manipulated as a percentage of a programmed reference value and the values for the last "Y" beats are stored in memory, where "Y" is a programmed value. The RVPPF value is also calculated as a percentage of a programmed value and the values thereof for the last "Y" beats are also stored in memory.

If "X" out of the last "Y" beats, where "X" and "Y" are programmed values, fail to produce RVFPPA and/or RVPPF values above programmed levels, then the PPU 24 communicates this to the MPU 20, indicating that a state of haemodynamic compromise exists.

It is noted that for both detection algorithms the presence of a bradycardia is defined in terms of an electrically sensed bradycardia, with or without the pressure sensor detecting haemodynamic compromise. Asystole is defined in terms of the absence of electrical activity and of modulation in the RVFPPA.

The invention can be implemented in either of two embodiments, using either of the above algorithms. In the first embodiment of the device VFPPA and VPPF are continuously derived. In the second embodiment, the haemodynamic sensor is activated only when an electrical abnormality in the function of the heart is detected.

In the first embodiment the MPU 20 continuously monitors PPU 24, as well as the electrical activity of the heart. The result generated by the haemodynamic compromise detection algorithm is used in conjunction with information gained electrically about the heart rate to determine what therapy to initiate. Since both electrical and haemodynamic function of the heart are being continuously sensed, an abnormality in the function of either can initiate therapy. The use of different sensitivities to detect different conditions in electrically derived signals is described in the copending United States Patent Application Serial No. 187,797 of R. Grevis and N. Gilli, filed April 29, 1988, and entitled "Apparatus and Method for Controlling Multiple Sensitivities in Arrhythmia Control System Including Post-Therapy Pacing Delay," which is assigned to the assignee of the present invention and is also incorporated herein by reference.

When a tachyarrhythmia is detected in accordance with the first embodiment of the present invention, therapy is initiated in accordance with the chart set forth in FIG. 1. It is noted that the chart of FIG. 1 is based on the use of a heart rate of 120 bpm as the dividing point between a tachyarrhythmia condition requiring electrical shock therapy and a condition not requiring antitachyarrhythmia electrical shock therapy. This value is a programmable initialization variable that would be set by the user/clinician based on his knowledge of and experience with the patient. It should also be pointed out that the use of a dual chambered configuration allows a lower energy cardioversion shock to be used to revert an atrial fibrillation that is haemodynamically compromising. This arrhythmia is recognized by the presence of an atrial rate that is higher than the ventricular rate, in the presence of haemodynamic compromise.

In the second embodiment of this device the MPU 20 will activate the PPU 24 to derive one of the RVFPPA and RVPPF values and initiate the programmed pressure sensing algorithm, as above, in the event that the device senses an electrical disturbance of the heart. It will then initiate therapy in accordance with the chart of FIG. 1. No therapy will be initiated if there is no evidence of haemodynamic compromise. The MPU 20 also periodically activates the PPU 24 to ensure that the FPPA and VPPF are within optimal normal limits. If they are not, then the MPU 20 will initiate its pacing optimization algorithm.

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delivered "Y" pacing pulses, as shown at 57, then capture is deemed to have occurred, as indicated at 59. If less than "X" pressure detections occur in response to "Y" pacing pulses, then capture is deemed not to have occurred, as indicated at 58.

Regardless of the method used to determine capture, if at any time a pressure pulse and/or a QRS wave is detected before a programmed time has passed, then a spontaneous contraction is deemed to have occurred. In this event, bradycardia support pacing is discontinued if the device is operating in an inhibited mode.

In the preferred embodiment of the invention, the device 7 is implemented to have VVI pacing (inhibited ventricular pacing and sensing). However, the device can be embodied to permit all standard pacing formats for dual and single channel pacing. In the event of dual channel pacing (i.e., both atrium and ventricle being paced) then a pressure sensor is required for both the atrium and the ventricle if the atrial pacing voltage is to be controlled.

In the preferred embodiment of the invention, maximum use is made of software control of the device. However, as indicated earlier, the device can be implemented using discrete circuitry, rather than software.

It will be apparent from the foregoing description that this invention provides an improved implantable, battery-operated device for the treatment of a malfunctioning heart that is capable of providing effective bradycardia support pacing at a lower mean energy level then has heretofore been the case in order to provide for increased battery life of the device. Moreover, the present invention provides such a pacemaker device having two sensing modalities for sensing both the heart's electrical function and its' haemodynamic function, and which utilizes sensed haemodynamic function information to enable it to reduce the bradycardia support pacing voltage to the lowest effective level. Also, the invention provides a two-sensing modality, cardioverting/defibrillating pacemaking device in which the energy required for bradycardia support pacing can be minimized by sensing evoked ventricular pressure responses to bradycardia support pacing. Similarly, improved methods are provided by the present invention (i) for determining a patient's need for bradycardia support pacing; (ii) for optimizing bradycardia support pacing voltages delivered to a patient's heart; and, (iii) for terminating ongoing bradycardia support pacing of a patient's heart when the need for such pacing no longer exists.

While particular embodiments of this invention have been shown and described, it will be obvious to those skilled in the art that various other changes and modifications may be made without departing from the invention in its broader aspects, and it is, therefore, aimed in the appended claims to cover all such changes and modifications as fall within the true spirit and scope of this invention.

Claims

1. An implantable, battery-operated device for the treatment of a malfunctioning heart, said device including a first sensing modality for sensing an electrical function of a patient's heart and providing a first signal representative of said electrical function, a second sensing modality for sensing an haemodynamic function of the patient's heart and providing a second signal representative of said haemodynamic function, first means responsive to said first signal for analyzing the state of the heart's function and providing any required electrical shock pacing therapy to the heart at an initial predetermined energy level high enough to ensure prompt pacing capture of the heart, and second means responsive to said second signal and operative when evoked haemodynamic responses from said pacing therapy are sensed to cause the energy level of said pacing therapy provided by said first means to be reduced from said initial predetermined level to a lower level, at which pacing capture of the heart can be maintained and battery life of the device is increased relative to the battery life obtainable at said predetermined energy level.

2. A device according to claim 1, wherein said second signal comprises the filtered peak-to-peak amplitude of a ventricular pressure waveform of the heart.

3. A device according to claim 2, wherein said second signal comprises the filtered and rectified integration of a ventricular pressure waveform of the heart.

4. A device according to any one of claims 1-3, wherein said ventricular pressure waveform of the heart is the right ventricular pressure waveform of the heart.

5. A device according to any one of claims 1-3, wherein said device comprises a dual chamber, cardioverting/defibrillating pacemaker.

6. An implantable, programmable, battery-operated device for sensing malfunctions in a patient's heart and

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vered to the heart; and, deeming pacing capture to have occurred in the event that the pressure waveform crosses a threshold value a predetermined number of times in response to an equal or a predetermined larger number of pacing pulses.

17. A method according to any one of claims 15 or 16, wherein the right ventricular pressure waveform of the heart is passed through a high-pass filter and digitized to provide a derived right ventricular peak-to-peak amplitude signal which is monitored for said programmed predetermined time to determine whether or not said threshold value has been crossed.

18. A method for determining the need for bradycardia support pacing of a patient's heart, comprising the steps of:
(A) continuously monitoring a signal derived from a haemodynamic pressure waveform of the patient;
(B) comparing said monitored signal with a predetermined threshold value;
(C) detecting when said threshold value is crossed by said monitored signal to determine when heart contractions have occurred; and,
(D) initiating bradycardia support pacing in the event a heart contraction does not occur within a predetermined time period following a last-detected heart contraction.

19. A method for determining the need for bradycardia support pacing of a patient's heart, comprising the steps of:
(A) continuously monitoring a signal derived from a haemodynamic pressure waveform of the heart;
(B) comparing said monitored signal with a predetermined threshold value;
(C) detecting when said threshold value is crossed by said monitored signal to determine when heart contractions have occurred; and,
(D) initiating bradycardia support pacing in the event a threshold crossing does not occur within a predetermined time period following the time at which the last-detected threshold crossing occurred.

20. A method for determining the need for continuing ongoing bradycardia support pacing of a patient's heart, comprising the steps of:
(A) continuously monitoring a signal derived from a haemodynamic pressure waveform of the patient during the application to the heart of bradycardia support pacing pulses;
(B) comparing said monitored signal with a predetermined threshold value;
(C) noting when said threshold value is crossed by said monitored signal to determine when heart contractions have occurred and;
(D) initiating a subsequent bradycardia support pacing pulse in the event a threshold crossing does not occur within a predetermined time period after a last-previous bradycardia support pacing pulse has been delivered.

21. A method according to any one of claims 18-20, wherein said signal is derived from a ventricular pressure waveform of the heart.

22. A method according to claim 21, wherein said signal comprises a high-pass-filtered, digitized representation of the right ventricular pressure waveform of the heart.

23. A method according to claim 21, wherein said signal comprises a rectified, integration of a high-pass-filtered, digitized representation of the right ventricular pressure waveform of the heart.

24. A method for terminating ongoing bradycardia support pacing of a patient's heart, comprising the steps:
(A) continuously monitoring both a first signal derived from a haemodynamic pressure waveform of the patient and a second signal representing electrical activity of the heart during the application to the heart of bradycardia support pacing pulses;
(B) comparing said monitored first signal with a predetermined threshold value and said monitored second signal with a predetermined QRS-wave complex; and,
(C) terminating said bradycardia support pacing if, within a first predetermined time after a last-previous bradycardia support pacing pulse has been delivered, either said first signal crosses a predetermined threshold value or said second signal displays a QRS-wave pattern within said predetermined QRS-wave complex.

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TYPICAL RATE, RVPPF AND RVFPPA VALUES DURING ARRHYTHMIAS.

(Rate expressed as beats per minute. RVPPF and RVFPPA expressed as a percentage of resting values).

RATE	RVPPF	RVFPPA	THERAPY
<=120	>60%	>80%	Normal pacing therapy
<=120	<60%	<80%	Pacing optimising algorithm
>120	>50%	>50%	Antitachycardia pacing
>120	>30% & <=50%	>30% & <=50%	Cardioversion
>120	<=30%	<=30%	Defibrillation

FIG. 1

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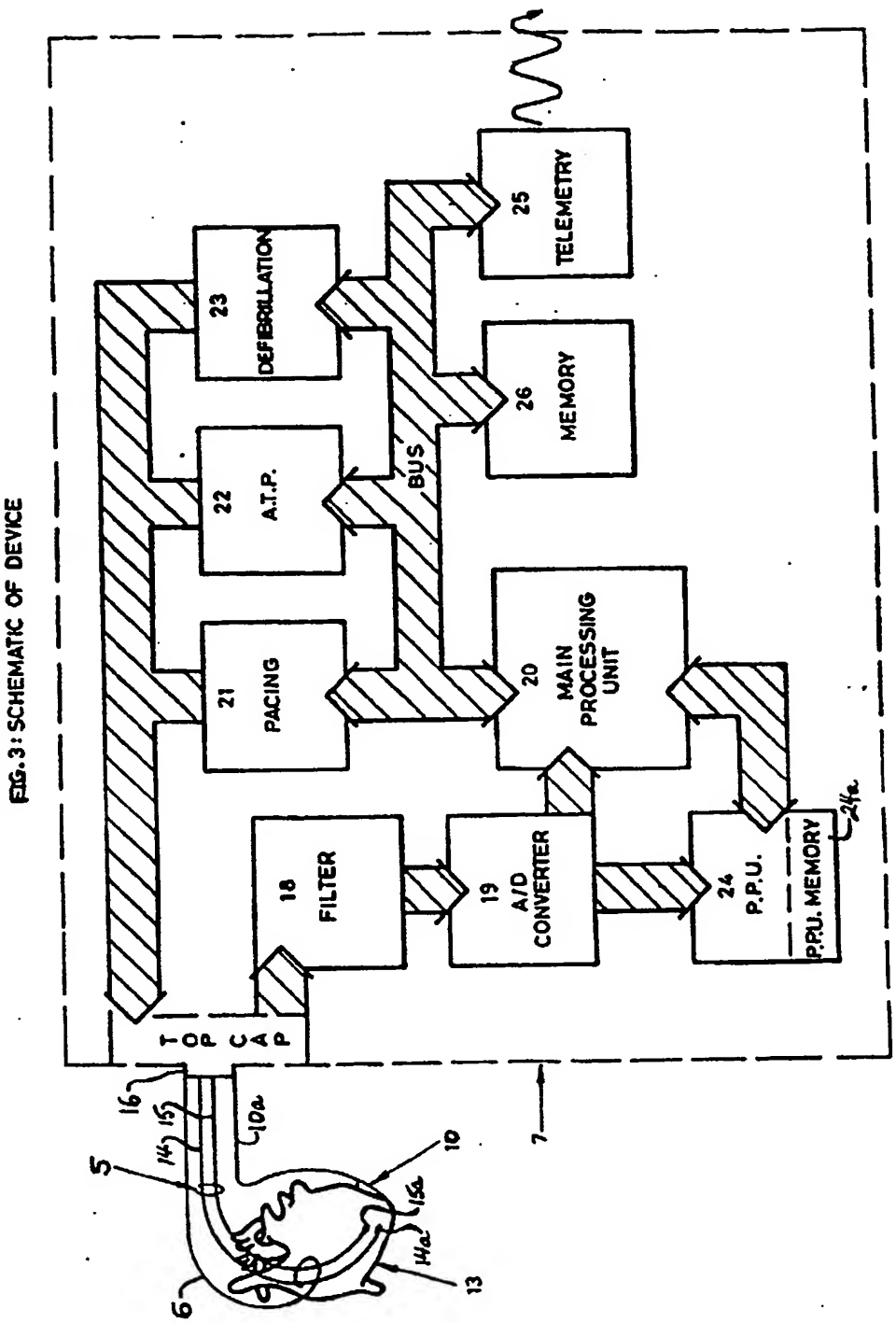

FIG.3: SCHEMATIC OF DEVICE

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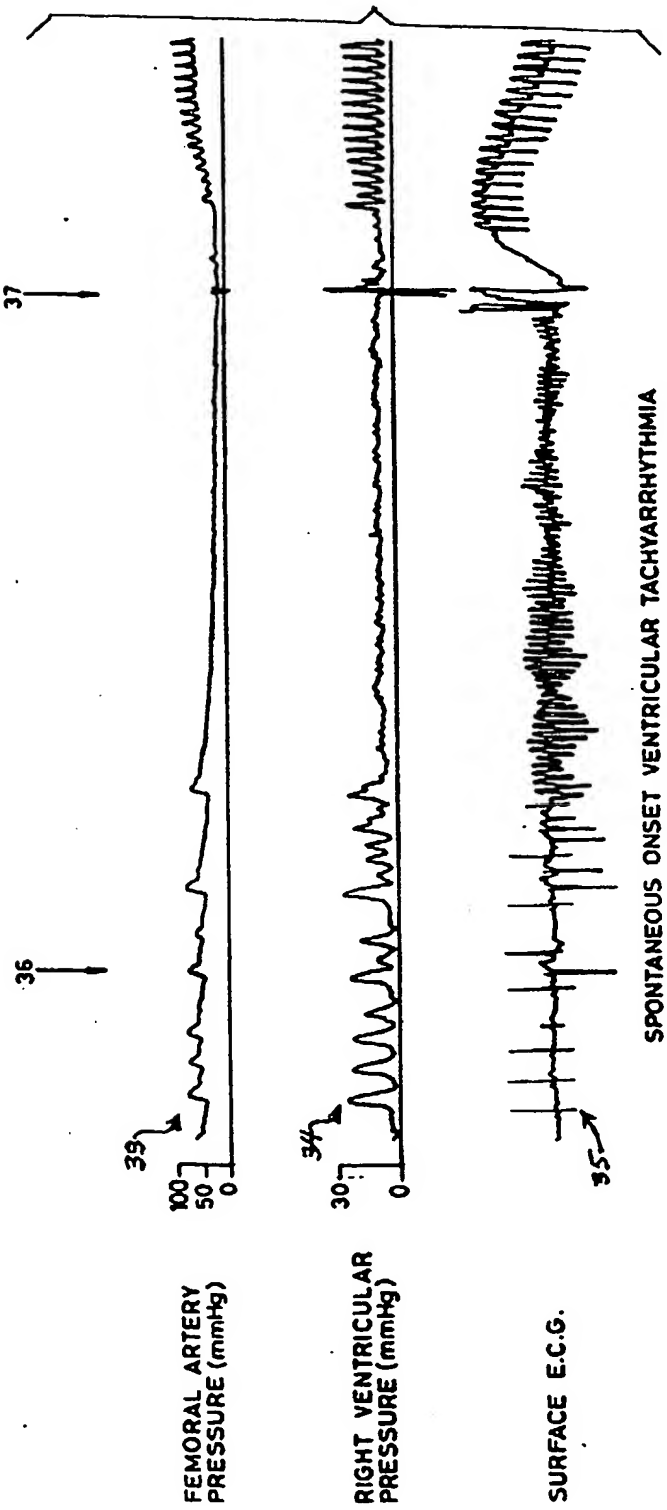

FIG.6

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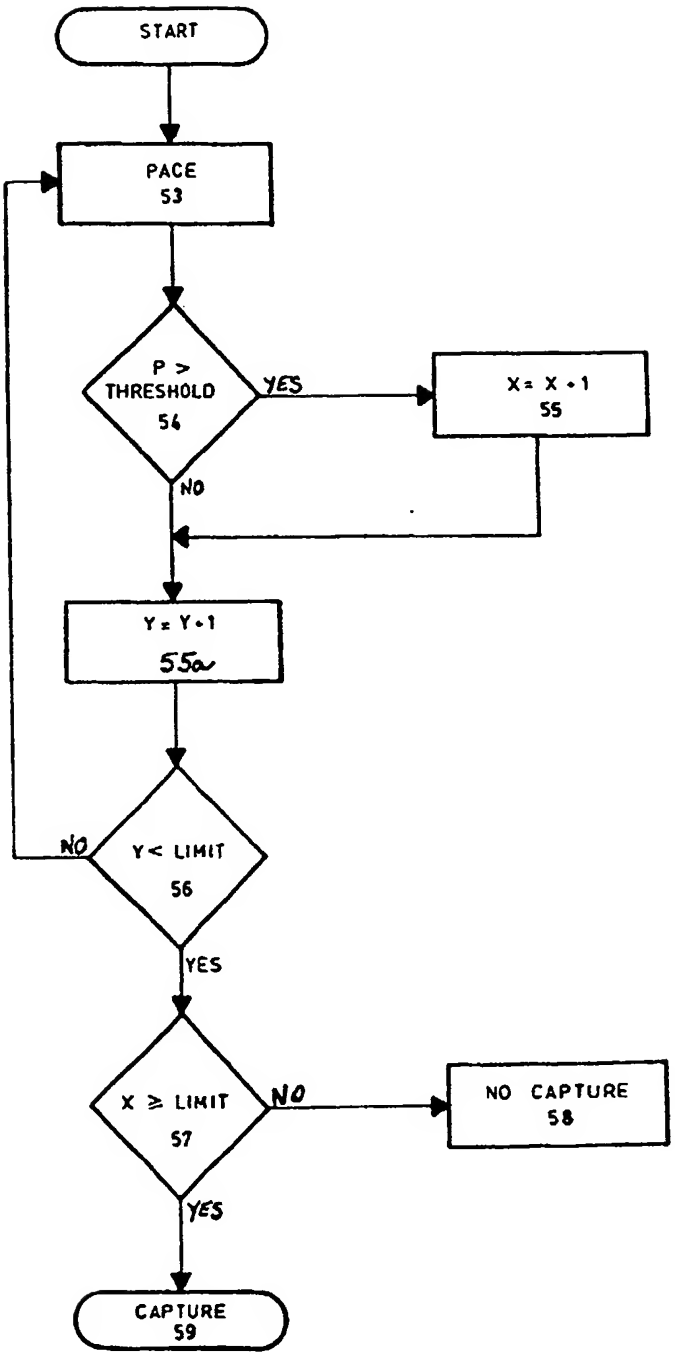
FIG. 8



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(71) Applicant : **TELECTRONICS N.V.**
De Ruyterkade 58A
P.O. Box 837
Curaçao (AN)

(72) Inventor : **Collins, Kenneth A.**
41 Shellcove Road
Neutral Bay, N.S.W. 2080 (AU)
Inventor : **Maker, Philip John**
22/15 Lachlan Avenue
North Ryde, Sydney (AU)

(74) Representative : **Sturt, Clifford Mark et al**
MARKS & CLERK
57-60 Lincoln's Inn Fields
London WC2A 3LS (GB)

(54) Implantable automatic and haemodynamically responsive cardioverting/defibrillating pacemaker with means for minimizing bradycardia support pacing voltages.

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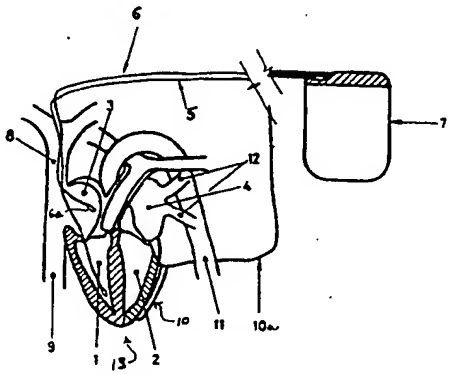

FIG. 2. SCHEMATIC OF HOW THE DEVICE IS TO BE DEPLOYED

1. RIGHT VENTRICLE
2. LEFT VENTRICLE
3. RIGHT ATRIUM
4. LEFT ATRIUM
5. RIGHT VENTRICULAR LEAD
6. RIGHT ATRIAL LEAD
7. DEVICE
8. SUPERIOR VENA CAVA
9. INFERIOR VENA CAVA
10. DEFIBRILLATION PATCH (ES)
11. AORTA
12. PULMONARY VESSELS
13. HEART
10a. DEFIB. PATCH LEAD

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